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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,570	09/15/2003	Luc R. Mongeon	1023-203US01	2842

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EXAMINER	
JASTRZAB, JEFFREY R	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/663,570	MONGEON, ET AL.	
	Examiner	Art Unit	
	Jeffrey R. Jastrzab	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *thru 10/4/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The process of making limitations fail to further limit the treatment method set forth in claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1- 35 are rejected under 35 U.S.C. 103(a) as being obvious over Stokes et al., US-6,567,705 in view of Lee et al., US-5,265,608.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a

showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Stokes et al. disclose the invention substantially as claimed less the genetic material being in a polymeric matrix for transport to a the patient. Stokes et al. do contemplate passive delivery, but do not give an example of a type. Lee et al. however teach the use of a polymeric matrix for the delivery of an active agent to a stimulating site in the analogous art of implantable nerve stimulation leads for the purpose of permitting the drug to be eluted at a desired rate. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have incorporated a polymeric drug elution system into the Stokes et al. device in order to effect rate control of the genetic material. As to Claims 2-6, modifying the type of matrix, given the Lee teaches would have amounted to an obvious choice in design absent any teaching of criticality or unexpected result. As to Claim 7, the method of making the matrix does not effect the resultant treatment method, further whether the physician or a prior

source assembles the lead, lacks patentable moment and would therefore have been obvious. A similar comment applies to Claim 8. As to Claim 9, the Examiner hereby takes Official Notice that porous electrode drug elution systems are notorious the passive drug delivery pacer lead arts. As to Claims 13-15, changing the genetic material to achieve a different effect dependent upon specific patient needs would have amounted to a routine diagnosis and treatment procedure and therefore obvious to the skilled artisan. As to Claim 16, drug cocktails are commonplace in drug treatment, merely adding a different supplemental genetic material would have involved routine treatment and thus lacking in patentable moment.

Claims 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stokes et al. and Lee et al. as applied to claims 1-35 above, and further in view of Farrar et al., US-6,565,777. As to Claims 36-39, although not specifically discussed in the Lee et al. invention, the making of the polymeric matrix would inherently require known techniques for blending and forming the polymeric matrix. Accordingly, merely adopting known freeze-drying techniques in the making of polymer drug matrices would have amounted to an obvious choice in manufacturing design.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 10/4/05, 5/23/05 and 3/24/05 have been considered.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. Jastrzab whose telephone number is (571) 272-4947. The examiner can normally be reached on M-W 5:30 a.m. to 4:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey R. Jastrzab
Primary Examiner
Art Unit 3762
5/1/06